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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/047,068	04/16/93	WEINBERG	J 200398800646

EXAMINER
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18M2/0824

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ART UNIT	PAPER NUMBER
1811	16

DATE MAILED: 08/24/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 6-30-93 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1—7 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1—7 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Claims 1-7 are pending in the instant invention. Claims 6 and 7 have been added as requested by applicant's in their communication filed June 30, 1993.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification provides no probative evidence to show the claimed utility of the method in suppressing T cell activation, inhibiting CD44-monocyte mediated IL-1 release or treating inflammation with CD44 protein is present in synovium of patients, however, the correlation between administration of CD44 protein, peptides or derivatives and inhibiting IL-1 release, suppressing T cell activation and inhibiting inflammation is unclear. Were peptides or derivatives ever administered <u>in vivo</u> or <u>in vitro</u> to show inhibition of cell adhesion, IL-1 release or

reduction of inflammation? Were monocytes ever depleted from the experimental cell population to determine the role of monocytes in CD44-mediated cell adhesion or IL-1 release? Applicant presents data on suppression of T cell activation in Table 6. This is unclear because there appears to be little effect of CD44-liposomes on the suppression of CD2 mediated T cell activation. What was the effect of CD44 without liposomes? It is unclear whether the effect on T cell activation was due to CD44 or solely to liposomes. Because of the aforementioned deficiencies in the specification and lack of guidance presented, it would require undue experimentation to practice the invention.

Claims 1-3, 6 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same

person.

Claims 1, 3, 6 are rejected under 35 U.S.C. § 103 as being unpatentable over Haynes et al. (1989) in view of St. John et al.

Haynes et al. describe the role of leukocyte adhesion molecules (CD44) in regulating T cell activation, monocyte mediated Il-1 release and in inflammation (page 173) during lymphocyte trafficking and homing to specific tissues Haynes et al. do not describe peptides or derivatives of the adhesion molecule. However, St. John et al. describe the sequence of the lymphocyte adhesion molecule (figure 4) and polypeptides which may be included in therapeutic preparations of the adhesion molecule effective in modulating autoimmune disease states such as rheumatoid arthritis, chronic site specific inflammatory conditions and adhesion-mediated entry of circulating lymphocytes into peripheral lymph nodes, mucosal organs and inflamed synovia (column 4, lines 18-55). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Haynes et al. on the role of CD44 adhesion molecule with the teachings of St. John et al. on polypeptides and other epitopes useful in therapeutic compositions of the leucocyte adhesion molecule with the expectation of a method of suppressing T cell activation in an animal, inhibiting CD44 monocyte-mediated IL-1 release and treating inflammation with the further expectation, in the

absence of a showing of unexpected results, that the method would be effective in reducing inflammation, inhibiting IL-1 release and suppressing T cell activation in an animal.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 4, 5 and 6 are rejected under 35 U.S.C. § 101 because the invention as disclosed is inoperative and therefore lacks utility.

Applicant's invention is directed to a method of preventing and treating HIV infection in an individual. Applicant's fail to present data demonstrating the in vivo utility of the claimed compounds nor does he show the utility of his compounds in an art accepted model correlated with human utility. Furthermore, the claims as written are of such incredible utility as to create a strong presumption of inoperativeness that can only be overcome by very clear objective evidence. See Ex parte Heicklen, 16 USPQ 2d 1463. There has been no effective means established that would prevent the infection of HIV. There have only been one or two limited treatments accepted in the HIV area. It is unbelievable on its face that applicant's have found an effective prevention or treatment of HIV infection in the absence of overwhelming evidence. For, Congress did not intend that a

patent be granted on a chemical compound, or a process for its production, whose sole "utility" consists of its potential role as an object of use testing. See Brenner, Comr. Pats V. Manson (USSC 1966) 383 US 519, 148 USPQ 689. For these reasons the claims have been rejected as inoperative and therefore lacking utility. See In re Ferens (CCPA 1969) 417 F2d 1072, 163 USPQ 609; Ex parte Moore et al. (POBA 1960) 128 USPQ 8; In re Hozumi et al., (Comr. Dec. 1985) 226 USPQ 353; and Rhone-Poulenc S.A. v. Dann (CA4 1974) 507 F2d 261, 184 USPQ 196.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Avis Davenport whose telephone number is (703) 308-4002.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MERRELL C. CASHION, JR.
SUPERVISORY PATENT EXAMINER
GROUP 180

AmD
Davenport/em
July 28, 1993